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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,795	11/14/2000	Harold G. Craighead	1153.010US1	8906

21186 7590 08/13/2004

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/712,795	Applicant(s) CRAIGHEAD ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 27-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 4/22/2004 has been received and entered into record and considered.

Currently, claims 1-61 are pending, claims 1-26 are under examination.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 4, "a second portion adapted for resonating" is vague and indefinite. It is not clear where this second portion is located, and what is the relationship between this second portion with the first immobilized portion. Applicant is reminded that it has been held that the recitation an element "adapted" to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Similarly, claims 6, 10-11 suffer the same problem.

Claim 1 is vague and indefinite ~~with~~^{with} respect to the recitation of a "system for detecting an analyte having mass" and that the structure resonates under ambient conditions at a frequency based on the mass of the analyte because it is unclear if the system detects changes in the mass on the surface of recited structure and relating this mass to the presence or amount of analyte. The recitation of "detecting an analyte having a mass" does not equate detecting the mass of analyte, only that the analyte has a mass, therefore, a system capable of detecting any analyte would meet this limitation, regardless of whether or not such a system is capable of detecting the mass of an analyte.

It is unclear how the immobilized portion and the second portion are arranged or whether they are in contact. The recitation of “wherein said structure has an immobilized binding partner that binds to said analyte on said second portion of the structure” is confusing since it is unclear if the second has immobilized binding partner on its surface or if the second portion has an immobilized analyte on its surface. If the second portion has an immobilized binding partner for analyte, then what is on the surface of the “immobilized portion” that defines it as an “immobilized portion”.

Claim 1 lacks a correlation between the output corresponding to a resonant frequency shift of the structure and any presence, absence, or mass of the analyte.

Claim 7, the recitation of “said second end” lacks antecedent support.

Claim 10 and 11 are vague and indefinite because it is unclear, for example, if the structure includes thermal noise or if the ambient condition is thermal noise.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-4, 6-9, 11-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebersole et al. (US 5756279).

Ebersole et al. disclose a composite sensor comprising a cross-linked analyte responsive polymer (ARP) containing analyte sensitive moieties attached to the surface of a sensor. A sample of test medium suspected of containing an analyte is brought into contact with the sensor and an analyte is brought into contact with the sensor and any analyte present interacts with the ARP to form a polymer-analyte complex. A propagational change is detected in the complex as compared to that of the uncomplexed ARP. The change is manifested as a change in resonance frequency of a piezoelectric oscillator or as a change in light propagation properties by a wave guide optical sensor or other optical detection device (Col. 7, line 32-44).

Ebersole et al. teach a method of detecting an analyte in a liquid sample by immobilizing a binding partner, e.g. antibody or antigen, on a biosensor surface, i.e. optical or piezoelectric sensor, to detect the resonance frequency shift due to the binding of analyte on the binding partner (See Figure 5 and 6; Col. 4, line 40-60). The claims have been broadly interpreted and that the sensor surface immobilized with the binding partner of Ebersole is equivalent to the instant "second portion" whereas the sensor itself is the "immobilized portion" of the structure. Furthermore, Ebersole et al. teach using a piezoelectric oscillator device for detection (Col. 14, line 35-45). Ebersole et al. also disclose that the detecting device can be applicable for detecting various analytes, including antigens, antibodies, cells, cellular subcomponents, biological receptors,

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chelating agents, DNA probe assays, microorganism, salt, ions (Col. 5, 60-67 to Col 6, line 1-10, line 12-20; line 28-36).

The optical system of Ebersole necessarily requires a light source. The optical system of Ebersole also comprises a guided light which is split into two parallel arms; one arm of the interferometer is coated with an analyte receptor while the other arm is protected to provide a reference path. As a result, light conducted into the wave guide is split into two beams. When analyte binding occurs, the refractive index at the surface of the receptor coated arm is altered whereas the effective index of the second beam does not change. When light in the interferometer arms are combined, constructive or destructive interference can occur (Col. 14, last paragraph to Col. 15, first paragraph).

5. Claims 1-11, 17-19, 21-23, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Quate et al. (US 6436647).

Quate et al. teach a sensor comprising microcantilevers to detect analytes in a sample. Quate et al. teach that immobilized binding partners, i.e. DNA sequence, on the tips of the cantilever fingers to bind to the target analytes where the binding can change the resonant frequency of the cantilever (Figure 1 and 2; Col. 4, line 10-22; claim 12). Quate et al. also use detectors, such as split photodiode, lineary array of photdetectors, piezoresistance detectors to detect the binding signals (Col. 5, line 55-60). The cantilevers taught by Quate et al. contain immobilized portion and a second portion, i.e. tip finger, for binding partner immobilization (See Figure 1 and 2). The material for the device can be of silicon (Col. 2, line 16-25). The cantilever device can be used to detect analyte binding caused by thermal change (See claim 12). Furthermore, Quate et al. disclose that immobilization of binding partners on the cantilever tips can also apply to "interdigital cantilevers" where they are structured as interleaved finger grid with first ends, second ends, and middle regions for immobilizing binding partners (Col. 6, line 45-50). Quate et al. disclose that the cantilever device can also be used in detection of protein array and polypeptide arrays (Col. 7, claims 7 and 8).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 24 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Quate et al. in view of Davis et al. (US 6311557).

With respect to claim 24, Quate et al. reference has been discussed but is silent in teaching a cantilever beam with the length of 0.5 to 1000 micron. Davis et al. review that advantages use of few hundred microns length cantilevers for simplicity and cost-saving purpose in detecting analytes in samples (Col. 1, line 40-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Quate et al. with the microcantilevers as taught by Davis et al. since the microcantilevers provide economical and convenience advantages in detecting analytes in samples.

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With respect to claim 26, applicant recites a structure comprises a disk-shape member having a perimeter and a center region, and wherein said immobilized portion includes said perimeter, and wherein said second portion includes said center region. It is considered that the design choice of modification of a device to optimize the intended use of said device is an obvious matter for one skilled in the art since such practice is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, since applicant has not disclosed as the specific limitation recited in the instant claims (disk-shape) are for any purpose or solve any stated problems, it is not inventive to offer a different choice of modification of a known device. Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have modified the device in a disk-shape and immobilizing the binding partners on the center region of the disk-shape sensor since it merely involves routine skilled in the art to optimize the shape to optimize the results.

Response to Applicant's Arguments

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

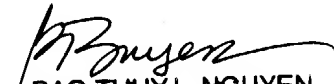
Jacob Cheu

Examiner

Art Unit 1641



August 5, 2004



BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/9/04